

Surgisleeve™ Wound Protector XS

K140064

510(k) Summary

SUBMITTER: Covidien
60 Middletown Avenue
North Haven, CT 06473 USA
Tel. No.: (203) 492-5000

CONTACT PERSON: Michael Koczocik
Product Specialist, Regulatory Affairs
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DATE PREPARED: January 2014

TRADE/PROPRIETARY NAME: Surgisleeve™ Wound Protector

Product Code(s) GCJ
KKX

COMMON/USUAL NAME: Wound Protector

CLASSIFICATION NAME: Endoscope and accessories per 21 CFR 876.1500
Surgical Drape and Drape Accessories per 21 CFR 878.4370

PREDICATE DEVICE(S): Applied Medical, Alexis™ Wound Retractors (K041711),
Covidien Surgisleeve™ Wound Protector (K120061)

DEVICE DESCRIPTION: Wound retraction device providing abdominal access and
Protection from wound contamination

INTENDED USE: The Surgisleeve™ Wound Protector is indicated for use to access the
abdominal cavity during surgery through an atraumatically retracted
incision, deliver maximum exposure of the abdominal cavity with
minimum incision size, and protect against wound contamination
during laparoscopic and open surgery. Additionally, the small size
Wound Protector is indicated for use to access the thoracic cavity
during cardiac and general surgical procedures through an
atraumatically retracted incision. The extra-small Wound Protector is
also indicated for use to access the thoracic cavity and other soft
tissue retraction during cardiac and general surgical procedures
through an atraumatically retracted incision.

**TECHNOLOGICAL
CHARACTERISTICS** The Surgisleeve™ Wound Protector Cylindrical Film is designed to
retract an incision and provide protection from wound contamination.
The interior and exterior rings are flexible to aid insertion, film
retraction, and removal.

MATERIALS: The Surgisleeve™ Wound Protector is comprised of materials that
have been evaluated in accordance with ISO 10993-1:2009, Biological
Evaluation of medical devices – Part 1: Evaluation and Testing.

Surgisleeve™ Wound Protector XS

PERFORMANCE DATA:

In-vitro and in-vivo testing to support the intended use of this device includes:

- Film Penetration Resistance
- Strength of Attachment Between Film and Proximal Ring, Distal Ring
- Film Weld Seam Strength
- In-Vivo Use:
 - Ring Insertion and Rolling,
 - Instrument Insertion and Removal,
 - Specimen removal,
 - Thoracic use,
 - Thoracic use specimen removal,
 - Digital ring removal

CONCLUSION:

The results of the performance evaluation demonstrate that the Surgisleeve™ Wound Protector (subject device) performed substantially equivalent to the predicate devices, the Alexis™ wound retractor (K041711) and the Covidien Surgisleeve™ wound protector (K120061).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 12, 2014

Covidien
Mr. Michael Koczocik
Product Specialist, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K140064
Trade/Device Name: Surgisleeve™ Wound Protector
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, KKK
Dated: January 10, 2014
Received: January 10, 2014

Dear Mr. Koczocik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Felipe Aguel

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Surgisleeve™ Wound Protector XS

Indications for Use

510(k) Number (if known): K140064

Device Name: Surgisleeve™ Wound Protector

Indications for Use:

The Surgisleeve™ Wound Protector is indicated for use to access the abdominal cavity during surgery through an atraumatically retracted incision, deliver maximum exposure of the abdominal cavity with minimum incision size, and protect against wound contamination during laparoscopic and open surgery. Additionally, the small size Wound Protector is indicated for use to access the thoracic cavity during cardiac and general surgical procedures through an atraumatically retracted incision. The extra-small Wound Protector is also indicated for use to access the thoracic cavity and other soft tissue retraction during cardiac and general surgical procedures through an atraumatically retracted incision.

Prescription Use X
(21 CFR 801 Subpart D)

AND/OR

Over the Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen
A

Digitally signed by Long H. Chen -A
DN: cn=Long H. Chen -A, ou=U.S. Government, ou=HHS,
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for BSA

(Division Sign-Off)

Division of Surgical devices

510(k) Number: K140064